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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,989	05/29/2001	Wilfred Wayne Lautt	2495.00071	7861

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,989

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 9-13 is/are allowed.
- 6) ☒ Claim(s) 5 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: _____

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DETAILED ACTION

The following is responsive to Applicant's amendment received Aug. 7, 2002.

Claims 6-8 are cancelled.

Claims 1-5 and 9-18 are currently pending.

All previous claims objections and rejections set forth in paragraphs 2-11 of the office action mailed Aug. 28, 2001 are withdrawn in view of the amendment and the remarks contained therein.

1. Applicant's arguments with respect to claims 1-5 and 9-18 have been considered but are moot in view of the new ground(s) of rejection.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 112

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 14 recites the limitation "The pharmaceutical composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

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Claims 1-4, 9-13 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed methods.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 5, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al., 6,165,975. (already of record)

Adams et al. teach pharmaceutical compositions comprising effective amounts of either sodium nitroprusside, 3-morpholinosydnonimine, molsidomine, S-nitroso-N-acetyl penicillamine (SNAP) and a pharmaceutically acceptable carrier. Please see abstract; col. 7, lines 33-47; col. 15, lines 1-67.

6. Claims 5, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Papandreou et al., 6,171,232. (Already of record).

Papandreou et al. teach that sodium nitroprusside is a generally approved nitric oxide donor pharmaceutical. Furthermore, other known nitric oxide pharmaceuticals include sodium nitrite and the Sydnonimines. Please see col. 6, lines 45-55.

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7. Claims 5, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Salzman et al., 5,958,427. (Already of record)

Salzman et al. teach pharmaceutical compositions comprising effective amounts of nitric oxide donor compounds. Please see the abstract; col. 2-6.

With respect to the claimed intended use of the composition to increase nitric oxide in the liver of a patient, the intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully submits that the prior art disclosed nitric oxide donor compositions are capable of increasing nitric oxide in the liver of a patient.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by either Klokke-Bethke et al., 5,370,862 or Veronesi et al., 5,580,576.

Klokke-Bethke et al. disclose pharmaceutical aerosol sprays containing effective amounts of the nitric oxide agonist, nitroglycerin. Please see the abstract; claim 1.

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Veronesi et al. disclose pharmaceutically/storage stable, water resistant formulations comprising nicorandil (a nitric oxide agonist) and pharmaceutically acceptable excipients. Please see the abstract; claim 1.

With respect to the claimed intended use of the composition to increase insulin sensitivity, the intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully submits that the prior art disclosed nitric oxide agonist compositions are capable of increasing insulin sensitivity.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al., 6,165,975 or Papandreou et al., 6,171,232 or Salzman et al., 5,958,427 or Klokke-Bethke et al., 5,370,862 or Veronesi et al., 5,580,576.

Said references as applied above.

However, these references do not specifically disclose formulating the compositions into a kit containing structural material; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of the prior art into kits because one of ordinary skill in the art would reasonably expect kit compositions to be a useful means for packaging pharmaceutical compositions for subsequent use in therapeutic treatment. This is further evidenced by Veronesi et al., which disclose packaging of tablets is known (please see col. 1, lines 65-67). Finally, the instructional material describing instructions for using the nitric oxide donor or agonist compositions relates to intended use and does not further limit or define the overall pharmaceutical compositions.

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Conclusion

Claims 1-4, 9-13 are free from the prior art.

Claims 5, 14-18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Dec. 16, 2002



Cybille Delacroix-Muirheid
Patent Examiner Group 1600